

Subject: SHIELDED Trocar with springloaded Obturator

510(k) # K960347

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A. Summary of Safety and Effectiveness:

1. Our "SHIELDED Trocar" was in detail compared to other, older Trocars and we concluded that our device provides safety for patients and operating room personnel. The cutting edge of our trocar is never exposed at any time.
2. Our SHIELDED Trocar establishes and maintains surgical access to the intra-abdominal cavity. It allows CO₂ insufflation and surgical Endoscopy identically to other, older trocars, with no difference in Effectiveness.

B. Parts of finding Substantial Equivalence:

1. The Intended Use and the Indications for Use are identical for our SHIELDED Trocar and the other, older Trocar versions.
2. The Design Engineering of our Trocar and older versions is identical in almost all components:

They all have:

1. A sharp cutting edge
2. A Trocar Sheath
3. Trocar Housing
4. A valve to minimize CO₂ loss
5. A Stopcock for CO₂ insufflation
6. A Sealing Cap

C. Descriptive Information

1. Our **SHIELDED** Trocar adds one feature to the old commonly known Trocar: It does not expose any sharp edges, except when it is pushed through the abdominal wall to gain surgical access. Then, inside of the body cavity, it automatically and immediately re-enters it's **SHIELDING MODE** by covering the cutting edge with a springloaded, blunt Obturator.

While assembled this new Trocar never allows accidental cutting of a patient or operating room personnel. Disassembly of this instrument is only required for cleaning and sterilization.

2. Our **SHIELDED** Trocar represents a combination between common old Trocars and the **SHIELDING** function of Veress needles: A springloaded blunt Obturator device always covers the sharp cutting edge.

D. Performance Testing

Comparative Bench testing with animal tissue enabled us to conclude that the performance and effectiveness of our **SHIELDED** Trocar is identical to older Trocar models.

E. Adverse Health Effects

We were not able to determine any adverse health effects with our **SHIELDED** Trocar and we cannot imagine any possibility of this kind.